

## ANNEX VII

### MONITORING PLAN

[<sup>F1</sup>This Annex describes in general terms the objective to be achieved and the general principles to be followed in the design of the monitoring plan referred to in Article 13(2), Article 19(3) and Article 20. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 30(2) in order to facilitate the implementation and explanation of this Annex.]

#### Textual Amendments

- F1** Substituted by [Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission.](#)

#### A. Objective

The objective of a monitoring plan is to:

- confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the e.r.a. are correct, and
- identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the e.r.a.

#### B. General principles

Monitoring, as referred to in Articles 13, 19 and 20, takes place after the consent to the placing of a GMO on the market.

The interpretation of the data collected by monitoring should be considered in the light of other existing environmental conditions and activities. Where changes in the environment are observed, further assessment should be considered to establish whether they are a consequence of the GMO or its use, as such changes may be the result of environmental factors other than the placing of the GMO on the market.

Experience and data gained through the monitoring of experimental releases of GMOs may assist in designing the post marketing monitoring regime required for the placing on the market of GMOs as or in products.

#### C. Design of the monitoring plan

The design of the monitoring plan should:

1. be detailed on a case by case basis taking into account the e.r.a.,
2. take into account the characteristics of the GMO, the characteristics and scale of its intended use and the range of relevant environmental conditions where the GMO is expected to be released,
3. incorporate general surveillance for unanticipated adverse effects and, if necessary, (case-) specific monitoring focusing on adverse effects identified in the e.r.a.:
  - 3.1. whereas case-specific monitoring should be carried out for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed or indirect effects which have been identified in the e.r.a.,

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- 3.2. whereas surveillance could, if appropriate, make use of already established routine surveillance practices such as the monitoring of agricultural cultivars, plant protection, or veterinary and medical products. An explanation as to how relevant information collected through established routine surveillance practices will be made available to the consent-holder should be provided.
4. facilitate the observation, in a systematic manner, of the release of a GMO in the receiving environment and the interpretation of these observations with respect to safety to human health or the environment.
5. identify who (notifier, users) will carry out the various tasks the monitoring plan requires and who is responsible for ensuring that the monitoring plan is set into place and carried out appropriately, and ensure that there is a route by which the consent holder and the competent authority will be informed on any observed adverse effects on human health and the environment. (Time points and intervals for reports on the results of the monitoring shall be indicated).
6. give consideration to the mechanisms for identifying and confirming any observed adverse effects on human health and environment and enable the consent holder or the competent authority, where appropriate, to take the measures necessary to protect human health and the environment.